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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,358	06/08/2000	Narendra Raghunathi Desai	273012008102	2416

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MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/25/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/589,358

Applicant(s)

Desai

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 16, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment dated 5-16-03 is acknowledged.

Claims included in the prosecution are 15-34.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 15-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,074,666.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth before.

Applicants indicate their willingness to file a terminal disclaimer. The rejection is still maintained in abeyance.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 15-20 and 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Madden (5,389,378).

Madden discloses Benzoporphyrins encapsulated in liposomes for photodynamic therapy of various cancers. The preparation is in a freeze-dried form and contains lactose. Madden teaches the use of a mixture of phospholipids and the lipids include DMPC and PG (note the abstract, col. 5, line 54 through col. 8, line 64, col. 9, lines 1 through line 62, Examples, Example 1 in particular and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. The essence of applicant's arguments appear to be based on the terms isotonic used by Madden and osmolarity used in instant claims. Applicant argues that tonicity and osmolarity are two distinct concepts and that tonicity is a relative terms. These arguments are not found to be persuasive. While tonicity might be a relative term, 'isotonic' is not a relative term. The examiner cites the reference of Wolff (6,265,387) which clearly teaches that hypertonic means that the osmolarity of the injection solution is greater than

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physiologic osmolarity and that isotonic means that the osmolarity of the injection solution is the same as the physiological osmolarity, i.e., the tonicity or osmotic pressure of the solution is similar to that of blood (col. 7, lines 38-45). The examiner also cites Baru (6,207,456) in this context (col. 3, lines 53-58).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 26-27 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden cited above.

Madden does not disclose the amounts of sugar in all of the claimed ratios. However, in view of Madden's teachings of the isotonic nature of the composition, it is deemed obvious to manipulate the amounts of the sugars and still achieve the isotonic nature of the composition as taught by Madden.

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the presumed lack of teaching of the osmolarity in Madden. These arguments have been addressed above.

7. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden as set forth above, further in view of Barenholz (4,797,285) already of record.

What is lacking in Madden is the teaching of inclusion of an antioxidant such as BHT.

Barenholz while disclosing drug containing liposomes, teaches that the inclusion of free-radical scavengers will prevent the oxidation of the compounds (note the abstract and col. 10, line 49 through col. 11, line 34).

The inclusion of a free-radical scavenger such as BHT in Madden would have been obvious to one of ordinary skill in the art since such an inclusion would prevent the oxidation of active agents as taught by Barenholz.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Barenholz does not teach the osmolarity. This argument is not found to be persuasive since Barenholz is combined for its teachings of the anti-oxidants; Teachings of Madden with regard to osmolarity have been discussed above.

8. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden as set forth above, further in view of applicant's statements of prior art.

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Madden does not teach all the porphyrin derivatives recited in instant claims. Instant specification appear to indicate that the claimed porphyrin derivatives are known. The use of art known porphyrin derivatives in the liposomes of Madden, with the expectation of obtaining similar results would have been obvious to one of ordinary skill in the art from the guidance provided by the prior art.

The inadvertent typographical error (inclusion of Thompson and Kappas) is regretted. Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the teachings of Madden which have been addressed above.

9. Claims 15-20 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319), further in view of Madden cited above.

Both Thompson and Kappas teaches liposomal porphyrins and photodynamic therapy (note the abstracts, Examples and claims in each).

What is lacking in these references is the teaching of the presence of sugars. What is also lacking in these references is the teaching that the osmolarity of the composition be the same of blood.

Crowe teaches that sugars protect liposomes during dehydration and rehydration (note the abstract, examples and claims).

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Madden as discussed above, teaches that when the liposomal compositions containing the porphyrins are administered parenterally, the compositions are and this could be achieved by the addition of salts, glucose or dextrose isotonic (note col. 10, lines 27-30).

The use of sugars in the liposomes of Thompson, and Kappas would have been obvious to one of ordinary skill in the art since sugars preserve liposomes during dehydration and rehydration steps. The addition of sugars would also have been obvious to one of ordinary skill in the art since these compounds are also helpful in making the compositions isotonic as taught by Madden.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the teachings of Madden which have been addressed above.

10. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319) and Madden as set forth above, further in view of Barenholz (4,797,285) already of record.

The teachings of Thompson, Kappas, Crowe and Madden have been discussed above.

What is lacking in these references is the teaching of inclusion of an antioxidant such as BHT.

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Barenholz while disclosing drug containing liposomes, teaches that the inclusion of free-radical scavengers will prevent the oxidation of the compounds (note the abstract and col. 10, line 49 through col. 11, line 34).

The inclusion of a free-radical scavenger such as BHT would have been obvious to one of ordinary skill in the art since such an inclusion would prevent the oxidation of active agents as taught by Barenholz.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the teachings of Madden which have been addressed above.

11. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden as set forth above, OR Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319) as set forth above, further in view of applicant's statements of prior art.

Neither Madden, Thompson or Kappas teach all the porphyrin derivatives in instant claims. Instant specification appear to indicate that the claimed porphyrin derivatives are known. The use of art known porphyrin derivatives in the liposomes of Madden, or Thompson or Kappas with the expectation of obtaining similar results would have been obvious to one of ordinary skill in the art from the guidance provided by the prior art.

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on the teachings of Madden which have been addressed above.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

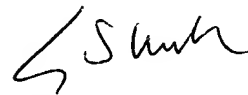
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 21, 2003